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July 11, 2000

Kathy Eberhart
Food and Drug Administration Center
for Biologics Evaluation and Research
1401 Rockville Pike, Suite 200 North
Rockville, MD 20852-1448
HFM42

Dear Ms. Eberhart:

As a practicing orthopedic spine surgeon, I would like to place my comments on the record regarding the FDA's proposal to regulate allograft tissue as a medical device. I strongly oppose such regulation. I have been using bone bank tissue since 1988 with no noted untoward side effects. I am aware that the tissue banks are diligent in providing safe and effective tissue for transplant and implantation.

Allograft material is useful to my patients on a daily basis for multiple orthopedic problems. It is my understanding that quality control measures are already in place by the tissue banks. It is my opinion that this is not a new implantable medical device which would require FDA supervision.

I strongly protest any regulatory process regarding allograft bone tissue as a medical device. I appreciate the opportunity to present these views to the FDA.

Sincerely

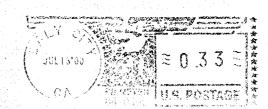
Paul J./ Slosar, M.D.

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